IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kamel KHALILI Group Art Unit: 1643

Application No.: 10/517,710 Examiner: Sheela J. Huff

Filed: July 27, 2005 Confirmation No.: 4632

Title: METHOD OF CELL GROWTH INHIBITION WITH AGNOPROTEIN

PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Mail Stop: PATENT EXT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This is a request for reconsideration of patent term adjustment for the application above, which issued as U.S. Patent No. 7,612,039 on November 3, 2009. This paper is filed in response to the Decision on Request for Patent Term Adjustment mailed September 28, 2009, attached in **Appendix B** of this paper. The present request is timely filed by January 4, 2010, because January 3rd falls on a Sunday. The present request is also filed with a fee pursuant to 37 C.F.R. § 1.18(e). Please charge any additional required fees or credit any overpayment¹ to our Deposit Account No. 50-0573.

Remarks begin on page 2.

A response under Rule 705d must comply *inter alia* with the requirements of Rule 705(b)(1), i.e., submission of a fee under 37 C.F.R. § 1.18(e). Patentees, however, fulfilled this requirement in their original Rule 705(b) submission filed May 27, 2009. Patentees do not interpret Rule 705 as requiring payment two fees to affect the same patent term adjustment. Patentees accordingly respectfully request reimbursement of the presently submitted fee.

REMARKS

In the Issue Notification, the Office determined that the patent term adjustment should be 221 days. However, in view of recent legal developments and as explained below, the patent term adjustment should be 459 days.

1. The Office Applied an Improper Method of Calculating Patent Term Adjustment

The U.S. District Court for the District of Columbia recently held that the Office has been applying an improper method of calculating patent term adjustment. *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008). The Patent Office applied that improper method in the present case, resulting in a 238 day error.

The statute governing patent term adjustment, 35 U.S.C. § 154(b), defines certain periods of Patent Office delay that give rise to extensions of patent term. These include an "A period" concerning Office failure to comply with certain deadlines (defined by 35 U.S.C. § 1.54(b)(1)(A)) and a "B period" concerning Patent Office failure to issue a patent within 3 years after the actual filing date of a patent application (defined by 35 U.S.C. § 1.54(b)(1)(B)).

In *Wyeth*, the Patent Office argued that any administrative delay under the A period overlaps any 3-year maximum pendency delay under the B period, such that delays should be credited to the A period or B period, but not to both periods. The court rejected that argument. It held that delays may be credited to both the A period and B period, except to the extent those periods overlap by occurring on the same calendar days. In view of *Wyeth*, Petitioners request reconsideration of the patent term adjustment for the subject patent.

2. Calculation of the A Period

The patent term adjustment history from PAIR (attached as **Appendix A**) shows an adjustment of 221 days in Patentee's favor for the A period. Term extension for the A period is based on a 324 day PTO delay to issue a non-final rejection plus a 30 day

PTO delay based on the 4-month period for the PTO to issue a patent, minus applicant delays of 133 days (i.e., 324 + 30 - 133 = 221).

3. Calculation of the B Period

The patent term adjustment history from PAIR (attached as **Appendix A**) shows an adjustment of 0 days for the B period. However, the B period should be 238 days. Relevant dates for calculating the B period are listed below:

National Stage commenced under 35 U.S.C. § 371(b) or (f): December 10, 2004 3-year Anniversary of commencement of National Stage: December 10, 2007 Request for Continued Examination (RCE): August 5, 2008

The patent issued November 3, 2009, 694 days after the 3-year anniversary of the filing date. However, time consumed by examination after a RCE does not count toward the B period. In this case, 456 days elapsed from the filing of a RCE until the patent issued. So the B period is calculated as follows:

694 days - 456 days = 238 days.

That is a difference of 238 days when compared with the Patent Office's improper 0 day calculation.

4. The Director Should Add 238 More Days to the Patent Term Adjustment

Considering the corrected B period, the Director should add 238 more days to the patent term adjustment. B period delays occurring on the same calendar days as A period delays constitute 0 days. Counting the 221 days of A period delays, the total term adjustment should be 221 + 238 = 459 days.

5. Presence or Absence of a Terminal Disclaimer

The patent is not subject to any terminal disclaimer that would impact such a correction.

CONCLUSION

Patentees set forth reasons above why the patent term should be adjusted 459 days, not 221 days as indicated in the Issue Notification. Patentees thus respectfully request grant of the present Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d).

Date: <u>December 30, 2010</u>

Respectfully submitted,

By: Brian K. Lathrop, Reg. No. 43,740

For: DANIEL A. MONACO Registration No. 30,480

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Attorney for Applicant

Attorney Docket No. 35926-0309-01-US (204136)
U.S. Patent No. 7,612,039, issued November 3, 2009
Request for Reconsideration under 37 C.F.R. § 1.750(d) dated December 30, 2010

Appendix A

Patent Term Adjustment calculation from PAIR

DC01/ 2434067.1

10/517,710	METHOD OF CELL GROWTH INHIBITION WITH AGNOPROTEIN						12-29- 2009::12:43:11	
Patent Term	n Adjustments							
		or Application Numb	per: 10/517,710					
Filing or 371(c) Date:	07-27-2005	USPTO Delay (PTC	Delay	y (days):		354
Issue Date of Patent:		11-03-2009	Three Years:					-
Pre-Issue Petitions (days):		+0	Applicant Delay (APPL) Delay (days):			ays):		133
Post-Issue Petitions (days):		+0	Total PTA (days):				221	
USPTO Adjustr		+0	Explanation Of Ca	lculatio	ns			
Patent Term	Adjustment H	listory	·.					
Date	Contents Desc		:		PTO(I	Days)	APPL(I	Days)
10-14-2009	PTA 36 Months							
11-03-2009	Patent Issue Da	te Used in PTA Calc	ulation			30		
10-02-2009	Dispatch to FDC			,		介	. *	
09-28 - 2009	Mail-Petition De	cision - Dismissed			. •	4		
09-28-2009	Petition Decision	n - Dismissed				4		
06-08-2009	Application Is C	onsidered Ready for	r Issue			•		
06-04 - 2009	Issue Fee Paym	ent Verified	· ,			介		
06-04-2009	Issue Fee Paym	ent Received						
05-2 7- 2009	Petition Entered	•						
03-20-2009	Sequence Forwa	arded to Pubs on Ta	pe					
03-06-2009	Mail Notice of A	lowance						
03-04-2009	Document Verif	cation						
03-04-2009	Notice of Allowa	nce Data Verification	on Completed					
01-27-2009	Date Forwarded	to Examiner						
01-05-2009	Response after	Non-Final Action						
10-08-2008	Mail Non-Final F	Rejection						
10-07-2008	Non-Final Rejec	tion						<i>i</i> .
08-05-2008	Information Dis	closure Statement	considered					
08-05-2008	Information Dis	closure Statement	(IDS) Filed					
08-14-2008	Date Forwarded	to Examiner					•	
08-14-2008	Date Forwarded	to Examiner						
08-05-2008	Request for Cor	tinued Examination	n (RCE)					4.
08-14-2008	Disposal for a R	CE / CPA / R129						1
08-05-2008	Information Dis	closure Statement	(IDS) Filed					1
08-05-2008	Workflow - Req	uest for RCE - Begi	n [*]					1
02-11-2008	Affidavit(s) (Ru	e 131 or 132) or E	xhibit(s) Received					1
03-19-2008	Mail Final Rejec	tion (PTOL - 326)						1
03-14-2008	Final Rejection							
03-06-2008	Date Forwarded	to Examiner						
02 - 11-2008	Response after	Non-Final Action						86
02-11-2008	Request for Ext	ension of Time - Gr	anted					1

08-17-2007	Mail Non-Final Rejection		324
08-14-2007	Non-Final Rejection	•	企
07-27-2005	Reference capture on IDS	·	1
12-05-2005	Cleared by OIPE CSR		4
11-24-2005	Cleared by OIPE CSR		企
11-24-2005	Cleared by OIPE CSR		會
11-24-2005	Cleared by OIPE CSR		1
11-24-2005	Cleared by OIPE CSR		4
11-24-2005	Cleared by OIPE CSR		企
11-18-2005	IFW TSS Processing by Tech Center Complete		1
11-18-2005	Case Docketed to Examiner in GAU		Ŷ
07-27-2005	371 Completion Date	·	1
11-01-2005	Application Dispatched from OIPE		1
11-02-2005	Notice of DO/EO Acceptance Mailed		介
07-27-2005	Additional Application Filing Fees		1
07-27-2005	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic		金金

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Attorney Docket No. 35926-0309-01-US (204136)
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Appendix B

Decision on Request for Patent Term Adjustment mailed September 28, 2009

DC01/2434067.1



Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.usoto.gov

DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA PA 19103-6996

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OFFICE OF PETITIONS

In re Application of

Kamel Khalili

Application No. 10/517710

Filing or 371(c) Date: 07/27/2005

Attorney Docket No.

06056-0309US1

: ON REQUEST FOR

: PATENT TERM ADJUSTMENT

This is in response to the REQUEST FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(b), filed May 27, 2009. Applicant submits that the correct patent term adjustment to be indicated on the patent is 429 days, not 191 days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicant requests this correction solely on the basis that the Office will take in excess of three years to issue this patent. The request is properly treated under 37 CFR 1.705(b).

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is **DISMISSED** as **PREMATURE**.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is

advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee¹.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries specific to this decision should be directed to Attorney Derek Woods at (571) 272-3232.

Alešia Brown

Senior Petitions Attorney

Office of Petitions

Office of the Deputy Commissioner

for Patent Examination Policy

For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the \\$1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.